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**Title:Safety of ERCP in Pregnancy: Fluoroscopy Time and Fetal Exposure, Does it Matter?**

**Author:** Ioana Smith1, Monica Gaidhane MD2, Allen Goode3, Michel Kahaleh MD2

**ESPS Manuscript NO:** 461

Dear Editor:

The manuscript has been improved according to the suggestions of reviewers:

* Title: “The Authors should include in the title the direct reference to the ERCP’ techniques used in this study”.
* Abstract: The estimated fetal radiation was expressed in Gy. The maximum allowed dose of radiation for the fetus was mentioned in the abstract.
* Introduction: Guidelines regarding the dose of radiation for the fetus were added.
* Methods: The US evaluation was eliminated.
* “Can the Authors explain more deeply the ERCP technique used in their work? Deep cannulation was effected with the sphincterotome, bile aspiration confirmed biliary position and a biliary sphincterotomy was then performed. The sphincterotome was then removed and replaced by a 12 mm extraction balloon into the bile duct. The extraction balloon was inflated and contrast administered.
* What are the major differences with standard technique? A systematic biliary sphincterotomy is performed and fluoroscopy only used once the balloon is inserted into the bile duct.
* What are the implications in radiation’s dose to the fetus? This was addressed but not in the methods section, this result in insignificant radiation for the fetus.
* Can the Authors report some details about the pre-ERCP diagnosis? How can they justify ERCP for cholelithiasis in pregnant women? We only performed ERCP in “symptomatic” cholelithiasis with high risk for cholangitis or pancreatitis.

* Can the Authors explain more accurately how they are evaluating that the 10% of the dose of TLDs on the upper back is considered to be the fetal dose? Different gestation ages and different mother’s constitution can determine different values of this parameters.

We agree that the depth dose will vary with both body habitus and gestational age, and, hence, the dose estimate as such is an approximation as defined in our original paper in 2004 (ref) Results: The fetal dose was reported in the results and the “estimated fetal radiation” was expressed in Gy. Complications were defined as being complications post-ERCP. Post-ERCP pancreatitis was pancreatitis that developed following ERCP and occurred in only two of our patients. The final Diagnosis of pancreatitis was seen in 14 patients and refers to pancreatitis existing in patients prior to ERCP but confirmed with ERCP and the visualization of the stone and its location. Modified technique refers to utilizing lead shielding to minimize radiation to the fetus therefore most ERCPs in pregnant women should implement the modified technique. The biochemical tests were within the normal range.

* Is ERCP performed on women with only US evaluation and normal biochemical tests? Only if the diagnosis is clear and unequivocal, to prevent repeat images, however in case were ultrasound is not diagnostic or unclear, an MRCP is typically offered.
* Can the Authors address more carefully the reasons why in pre-ERCP diagnosis there are 17 biliary acute pancreatitis and in final diagnosis there are only 14 in this category? Pre-diagnosis was based on clinical assessment ie symptoms, ultrasound, and labs. Inherently, discrepancies exist between clinical “pre-ERCP” diagnosis and “post-ERCP” diagnosis given the benefit of extracting the stone during ERCP procedure.
* It might be helpful also adding in the Table 1 the percentages of complication reported in previous studies and comparing them with the present work? We added the complications section and also updated the Table as requested
* Discussion: ESE was replaced by ERCP induced fetal radiation.
* The small population size is an important limitation. Difficult ERCP cannulation cannot be included because the sample size is too small. Our population of 35 pregnant women undergoing ERCP is second in number to Tang et al study published in 2009.
* The Authors affirmed that “for a routine ERCP with modified techniques, estimating the fetal radiation exposure from the fluoroscopy time and measuring it with the use of TLD’S is unnecessary”. However in the next sentence the Authors report that “The threshold may be exceeded in complicated long-lasting ERCPs and in these complicated long-lasting ERCPs, dosimetry may be used to estimate the fetal radiation exposure”. Can the Authors address and comment on their evaluation of the duration time of the procedure at the beginning of the ERCP? Based on the information available, the endoscopist is often able to identify in most cases, patients in whom the ERCP may be complicated, for instance “altered anatomy, failed ERCP at another institution, complex bile leak etc… In those patients, dosimetry might be used to estimate the fetal radiation exposure.
* References: References were updated. The following references were included:

“ERCP during pregnancy.” García-Cano J, Pérez-Miranda M, Pérez-Roldán F, González-Carro P, González-Huix F, Rodríguez-Ramos C, Naranjo A, González-Martín JÁ, de la Serna C. Rev Esp Enferm Dig. 2012 Feb;104(2):53-8. PMID: 22372797.

“ERCP in pregnancy: is it safe?”. Daas AY, Agha A, Pinkas H, Mamel J, Brady PG. Gastroenterol Hepatol (N Y). 2009 Dec;5(12):851-5. PMID: 20567530

“Two stage endoscopic approach for management of choledocholithiasis during pregnancy.” Sharma SS, Maharshi S. J Gastrointestin Liver Dis. 2008 Jun;17(2):183-5. PMID: 18568140

“Endoscopic intervention for symptomatic choledocholithiasis in pregnancy”. Krishnan A, Ramakrishnan R, Venkataraman J. Clin Res Hepatol Gastroenterol. 2011 Nov;35(11):772-4. Epub 2011 Sep 28. PMID: 21955516

Thank you again for publishing our manuscript in your prestigious journal.

Best Regards,

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